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10/711,156	08/27/2004	Bryan E. GARNER	5233.012.NPUS01	5155

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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/711,156	GARNER, BRYAN E.	
	Examiner	Art Unit	
	AMANDA SHAW	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/31/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16 and 17* is/are rejected.

7)☒ Claim(s) *2 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed December 31, 2007. This action is made non-final.

Claims 1-10 and 16-17 are currently pending and have been addressed herein.

Withdrawn Rejections

2. The rejections made under 35 USC 103(a) in sections 5-6 of the Office Action of August 29, 2007 are withdrawn in view of the Applicants arguments on pages 2-6 in the response filed December 31, 2007. The Applicants main argument is that Yamamoto specifically excludes an incubation step with MPN is combined with PCR. This argument has been found persuasive.

Specification

3. The disclosure is objected to because the first paragraph of the disclosure refers to Disclosure Document No 529733, received April 15, 2003, entitled "Analyzing Probiotics in Animal Feed". The Applicants are reminded that the first paragraph of the disclosure should only refer to prior filed applications that are claiming benefit under 35 USC 120, 121, 365(c) or 119(e). See MPEP 201.11. Appropriate correction is required.

Claim Objections

4. Claim 2 is objected to because of the following informalities: there appears to be a typo in claim 2. Specifically claim 2 refers to "at least one **oglionucleotide**". Appropriate correction is required.

Claim 17 is objected to because of the following informalities: there appears to be a typo in claim 17. Specifically claim 17 refers to "the method as claimed in claim 6", however it appears that claim was actually supposed to depend from claim 16. If this is true appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4, and 10 recite the limitation "the specific kind of microorganism". There is insufficient antecedent basis for this limitation in the claim because the claims do not previously refer to “a specific kind of microorganism”. Further it is unclear if a "specific kind of microorganism refers to a specific genus of microorganisms, a specific species of microorganisms or something else.

Claim 2 is indefinite over the recitation of the phrase "wherein said PCR analysis comprises at least one oligonucleotide". This phrase in considered unclear how a

method such as PCR can comprise a product such as an oligonucleotide. However, methods can comprise using products.

Claim 3 recites the limitation “the respective portions”. There is insufficient antecedent basis for this limitation in the claim because the claims do not previously refer to a “respective portion”. Further it is unclear what is encompassed by the phrase “respective portion”.

Claim 7 is indefinite over the recitation of the phrase "incubated sample which includes detecting...". This phrase in considered indefinite because it is unclear what the “which includes” language modifies. For example does this language refer to the PCR or something else.

Claim 8 is indefinite over the recitation of the phrase "incubated test samples which includes using...". This phrase in considered indefinite because it is unclear what the “which includes” language modifies. For example does this language refer to the PCR or something else.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 4-8, 10, and 16-17 are rejected under 35 U.S.C. 103(a) as being obvious over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology 1997).

Miwa teaches using the most probable number method combined with nested PCR for the detection and enumeration of bacteria in the intestinal contents of cattle, pig and chicken. Ten fold serial dilutions of samples were added to three tubes of enrichment medium, which were incubated at 37°C for 20-24 hours and then analyzed by PCR analysis (Abstract). Thus Miwa teaches a method comprising obtaining a liquid suspension sample comprising a viable microorganism, preparing a series of progressively dilute test samples, incubating the series of progressively dilute test samples, conducing PCR analysis on the series of progressively dilute test samples, and using the most probable number model to determine the concentration of viable microorganism in the sample as required by claim 1. Miwa teaches that ten fold serial dilutions of samples were added to three tubes of enrichment medium, which were incubated at 37°C for 20-24 hours and then analyzed by PCR analysis (Abstract). Thus Miwa teaches a method wherein the samples were prepared by dividing the sample into multiple portions (i.e. three test tubes) and incubating each portion wherein the microorganism was detected in each portion as required by claim 4. Further Miwa teaches a method wherein the samples were diluted and then divided into multiple samples (i.e. 3 test tubes) as required by claim 5. Additionally Miwa teaches a method wherein the samples were diluted by mixing the sample with a liquid to produce a fluid

mixture and then dividing the fluid mixture into multiple samples (i.e. 3 test tubes) as required by claim 6. Miwa teaches that Clostridium perfringens is a microorganism that causes food position, therefore Miwa teaches a method wherein the microorganism of interest is a harmful or undesirable organism as required by claims 16-17.

Miwa does not teach a method wherein the sample is obtained from a food product. Additionally Miwa does not exemplify using at least one oligonucleotide and detecting the presence or absence of a product of hybridization as required by claim 7. Further Miwa does not exemplify using two oligonucleotide primers to detect the presence or absence of a product of the PCR reaction as required by claim 8. Miwa does not exemplify a method wherein the detecting of the presence or absence of a product includes performing electrophoresis as required by claim 10.

However Mantynen teaches a method which utilizes a most probable number PCR assay for detection and enumeration of enterotoxin C producing Staphylococcus aureus from fresh cheese (Abstract). Mantynen teaches that S. aureus was grown and a known amount was added to 1 liter of milk. The milk was then used to make fresh cheese (Page 136, column 2 to Page 137, column 1). Thus Mantynen teaches a method wherein the sample is obtained from a food product. Mantynen teaches that for enumeration of S. aureus from cheese, ten fold dilution series from all of the samples were prepared and subjected to PCR. Mantynen teaches that two PCR primers that are specific for the detection of the entC1 gene of S. aureus were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification (Page 138, Column 2).

Therefore Mantynen teach a method of using at least one oligonucleotide and detecting the presence or absence of a product of hybridization as required by claim 7 since if the primers cannot hybridize to the target a PCR product is not formed. Mantynen further teaches that they were able to detect a 801 bp fragment of the entC1 gene using primers 1 and 2 and they were also able to detect a 631 bp fragment of the entC1 gene using primers 3 and 4 (Fig 1). Thus Mantynen teaches using two oligonucleotide primers to detect the presence or absence of a product of the PCR reaction as required by claim 8. Mantynen teaches a method wherein the detecting of the presence or absence of a product includes performing electrophoresis as required by claim 10 (Fig 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Miwa to the detection of microorganisms that are present in food products as suggested by Mantynen. Particularly Mantynen teaches that certain Staphylococcus aureus strains produce heat stable enterotoxins which can cause food poisoning. Therefore one would have been motivated to use the method of Miwa to quantify microorganisms such as S. aureus in food samples in order to make sure the food product will not cause food poisoning.

8. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology 1997) as applied to claims 1 and 8 above and in further view of Lucchini (Federation of European Microbiological Societies 1998).

The teachings of Miwa and Mantynen are presented above.

The combined references do not teach a method wherein one PCR primer hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism.

However Lucchini et al teach a method wherein multiplex PCR was performed using four oligonucleotide primers. Two genus specific primers named LARNA5 and LARNA6 were used. These primers were specific to a conserved region of 248 bp within the 16S rRNA gene of lactobacilli. Two species-specific primers named APF3 and APF4 were also used. These primers were specific to L. gasseri (Page 274, column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Miwa and Mantynen so as to have used one PCR primer which hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism for the added benefit of being able to distinguish between different species when more than one species is suspected of being present in the sample to be tested.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology

1997) as applied to claim 1 above and in further view of Savill (Journal of Applied Microbiology 2001).

The combined teachings of Miwa and Mantynen are presented above.

The combined references do not teach a method wherein the sample is cultured on a plate of culture media and the respective poritions of the cultured sample are taken from respective colonies that have grown on the pate.

However Savill teaches using PCR in tandem with MPN to enumerate microorganisms in water samples (Abstract). Savill teaches that DNA was prepared fro PCR using a crude heat lysis method. In this method a large loopful of fresh bacterial culture was harvested from an agar plate and suspended in extraction buffer. Lysis was then performed (page 40). Thus Savill teaches a method wherein wherein the sample is cultured on a plate of culture media and the respective poritions of the cultured sample are taken from respective colonies that have grown on the pate.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Miwa and Mantynen by culturing the sample on a plate of culture media as suggested by Savill. In the instant case all of the claimed methods were know in the prior art and one of skill could have combined these methods and the combination would have produced predictable results.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 16-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, and 9-15 of Application No 10711155. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-10 and 16-17 are generic to all that is recited in claims 1, 7, and 9-15 of Application No. 10711155. That is, claims 1-10

and 16-17 of Application No 10711155 fall entirely within the scope of claims 1, 7, and 9-15 or, in other words, claims 1, 7, and 9-15 are anticipated by claims 1-10 and 16-17 of Application No. 10711155. Specifically, both sets of claims encompass methods for quantifying the presence of a microorganism in a sample of material using at least one oligonucleotide. The present claims allow the detection of any type of microorganism in any type of sample by culturing the sample and using an oligonucleotide to detect the microorganism. The claims of the Application No. 10/711155 are specific for the detection of Lactobacillus, L. acidophilus, and Lactobacillus LA-51 in samples of animal feed that are transported from an animal feedlot to a laboratory for culturing and using an oligonucleotide to detect the microorganism. Accordingly, the detection of these specific microorganisms in animal feed is encompassed by the presently claimed methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

11. In the response filed December 31, 2007, Applicants stated that pending client documentation a terminal disclaimer will be filed to overcome the non-statutory double patenting rejection. As of the date that this Office Action was created the Office has not yet received the terminal disclaimer. Accordingly, the rejection is maintained.

Conclusion

12. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SHAW whose telephone number is (571)272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Juliet C Switzer/
Primary Examiner, Art Unit 1634